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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,788

01/28/2005

Yoshiharu Yamazaki

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

03/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,788	Applicant(s) YAMAZAKI ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1,6-8,10-12,15,17,18 and 21-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5,9,13 and 16 is/are rejected.
- 7) ☒ Claim(s) 14, 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/17/05; 11/9/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election without traverse of the invention of Group I and the Species of Figure 10 in the reply filed on August 4, 2008 is acknowledged.

Claims 2-5, 9, 13, 14, 16, 19 and 20 were designated as reading on the elected species. Claim 1, 6-8, 10-12, 15, 17, 18 and 21-33 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 lacks proper antecedent basis for "the coating materials of the lead wires....of the temperature sensor".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (4,946,440) in view of the teachings of Lennox et al (4,955,377) and Wijay et al (4,921,483).

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Hall discloses a catheter comprising a double cylinder structure having an inner shaft (16) slidably inserted into an outer shaft (12). A balloon (18) is attached between the tip portion of the inner shaft and the tip portion of the outer shaft (Figures 3 and 4), and Hall disclose a HF wire (86) provided inside the balloon. Hall fails to specifically disclose the use of two electrodes, providing a temperature sensor in the balloon, or the particular tube attached to the inner shaft and being softer than the inner shaft.

Regarding the use of multiple electrodes and temperature sensors, the examiner maintains that it is generally known in the art to provide bipolar electrodes and temperature sensors in RF balloon devices. Lennox et al disclose an analogous RF balloon catheter device and specifically teach that it is known to provide a pair of electrodes (22,24) within a balloon device, and further disclose the use of a temperature sensor (26) for monitoring temperature and controlling the delivery of RF energy.

Regarding the provision of a soft tip attached to the inner shaft, Wijay et al disclose another catheter for angioplasty procedures and teach that it is advantageous to provide the distal end of the catheter with a tube (T - Figure 4) that is softer than the inner shaft (Abstract) and that extends from the inner shaft to provide a safer distal end for introduction through the vasculature.

Regarding claims 3-5, Wijay et al also disclose a side-hole in the tube (Figure 6), as well as the use of various copolymers for making the tube (col. 10, lines 19-21). The particular hardness gradient and the recovery rate of the material are deemed to be obvious design parameters for those of ordinary skill in the art.

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Regarding claim 13, the specific inductive capacity of the shafts and the lead coatings are deemed to be within the purview of the skilled artisan.

To have provided the Hall device with two electrodes and a temperature sensor in the balloon member for heating the balloon and controlling the delivery of energy, respectively, would have been an obvious design modification for one of ordinary skill in the art in view of the teaching of Lennox et al. To have further provided the Hall et al device with a soft tube extending from the inner shaft to provide for safe introduction of the device through the vasculature would have been an obvious modification for the skilled artisan in view of the teaching of Wijay et al.

Claims 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (440), Lennox et al ('377) and Wijay et al ('483), and further in view of the teaching of Strul (5,498,261).

Hall, as addressed previously, fails to disclose a temperature sensor fixed in the electrode as recited in claim 9 or a sensor at the tip of the balloon.

Strul discloses an analogous RF heating balloon for angioplasty and specifically disclose a temperature sensor (20) carried by the electrode member (18). Strul further discloses the use of multiple sensors (22) located at different locations on the balloon, and to have provided a sensor at any desired location (e.g. a tip) would have been an obvious consideration for one of ordinary skill in the art to receive thorough temperature information across the balloon.

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To have provided the Hall device, as modified by the teachings of Lennox et al and Wijay et al, with a temperature sensor fixed to the electrode would have been an obvious design modification for the skilled artisan since Strul fairly teaches it is known to provide a temperature sensor affixed to the electrode in an analogous device. The particular location for the electrode is deemed an obvious design consideration for the skilled artisan as those of skill in the art recognize that sensors may be located at various locations within the balloon (as evidenced by Strul).

Allowable Subject Matter

Claims 14, 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art fails to disclose the particular shielding pipe or the anti-elongation string as set forth in these claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Satake (6,491,710), Mueller et al (5,041,089), Tu et al (6,102,908) and Maguire et al (6,500,174) all disclose various balloon devices having electrodes for heating tissue. Ellis et al (5,676,654) discloses another balloon device having the balloon coupled between movable inner and outer shafts, and Fugoso et al (5,643,209) disclose another balloon catheter that has a soft tip attached to the inner shaft for atraumatic introduction into blood vessels.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
February 11, 2009